K053210

JAN 6 2006

510(k) SUMMARY

Schaerer Mayfield USA, Inc.'s Mayfield® ScanMate™ Mobile CT System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Schaerer Mayfield USA, Inc.
4900 Charlemar Drive
Cincinnati, OH 45227

Phone: (513) 561-2241
Facsimile: (513) 561-0195

Contact Person: Teck W. Awa

Date Prepared: November 1, 2005

Name of Device and Name/Address of Sponsor

Mayfield® ScanMate™ Mobile CT System

Schaerer Mayfield USA, Inc.
4900 Charlemar Drive
Cincinnati, OH 45227

Common or Usual Name

Computed Tomography X-ray System

Classification Name

Computed Tomography X-ray System

Predicate Device(s)

Analogic Corporation's ANATOM 2000

Intended Use / Indications for Use

The Mayfield® ScanMate™ Mobile CT System is a whole body CT scanning system. It is intended for use as a Computed Tomography X-ray System for diagnostic purposes, producing cross-sectional images of the body through computer

reconstruction of X-ray transmission data from the same axial plane taken at different angles.

The Mayfield® ScanMate™ Mobile CT System is indicated for use as a Computed Tomography X-ray System for diagnostic purposes, producing cross-sectional images of the body through computer reconstruction of X-ray transmission data from the same axial plane taken at different angles.

Technological Characteristics

The Mayfield® ScanMate™ Mobile CT System consists of gantry, operating console with display, and patient support device. The gantry is light-weight and uses a translatable rotating disk with X-ray generator and tube, pre-collimator, 384-element solid state detector array, control computer, communication link, data acquisition, energy storage banks, and power management and supply electronics. The gantry can translate horizontally approximately ±7" (±178 mm) for a total travel distance of approximately 14 inches (356 mm) and can be tilted +30/-25 degrees from the vertical. The patient support device is not electronically connected to the gantry. It consists of a radiolucent extension that is either attached to a surgical table or used with a hospital bed. During scanning, the patient support device remains stationary and the gantry translates horizontally to provide the scan increment. The operator console consists of a Sun Sparc 5 computer and keyboard, 17" monitor, audio system, emergency controls, and uninterruptible power supply. The work station is responsible for the control-selection of the gantry, image processor, X-ray generator and tube.

Substantial Equivalence

The Mayfield® ScanMate™ Mobile CT System is as safe and effective as the ANATOM 2000. The Mayfield® ScanMate™ Mobile CT System has the same intended uses, indications for use, technological characteristics, and principles of operation as its predicate device, except that the ScanMate Mobile CT System uses a radiolucent extension attached to either an operating table or patient bed as a patient support, rather than a translatable patient support. This minor technological difference between the device and its predicate device raise no new issues of safety or effectiveness. Thus, the Mayfield® ScanMate™ Mobile CT System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Schaerer Mayfield USA, Inc.
% Mr. Jeffrey K. Shapiro
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K053210
Trade/Device Name: Mayfield® ScanMate™ Mobile CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 16, 2005
Received: November 16, 2005

Dear Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K053210

Device Name: Mayfield® ScanMate™ Mobile CT System

Indications for Use:

The Mayfield® ScanMate™ Mobile CT System is intended for use as a Computed Tomography X-ray System for diagnostic purposes, producing cross-sectional images of the body through computer reconstruction of X-ray transmission data from the same axial plane taken at different angles.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ____ of ____

David A. Lagrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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